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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/271,411 03/17/99 NORTHRUP

M 22660-0009P1

HM22/0131
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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

Handwritten '7' above the date.
01/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Northrup et al.

Ardin Marschel

1631

Table 1. Demographic characteristics of the study population		Table 2. Demographic characteristics of the study population	
Characteristic	Frequency	Characteristic	Frequency
Age (years)		Gender	
18-24	10	Male	10
25-34	10	Female	10
35-44	10	Marital status	
45-54	10	Married	10
55-64	10	Single	10
65-74	10	Divorced	10
75-84	10	Widowed	10
85-94	10	Education level	
95-104	10	High school	10
105-114	10	College	10
115-124	10	Postgraduate	10
125-134	10	Occupation	
135-144	10	Student	10
145-154	10	Professional	10
155-164	10	Managerial	10
165-174	10	Service	10
175-184	10	Unemployed	10
185-194	10	Retired	10
195-204	10	Income (USD)	
205-214	10	Low	10
215-224	10	Medium	10
225-234	10	High	10
235-244	10	Health status	
245-254	10	Good	10
255-264	10	Fair	10
265-274	10	Poor	10
275-284	10	Very poor	10
285-294	10	Unknown	10
295-304	10	Smoking status	
305-314	10	Smoker	10
315-324	10	Non-smoker	10
325-334	10	Alcohol consumption	
335-344	10	Regular	10
345-354	10	Occasional	10
355-364	10	Never	10
365-374	10	Exercise frequency	
375-384	10	Daily	10
385-394	10	Weekly	10
395-404	10	Monthly	10
405-414	10	Never	10
415-424	10	Stress level	
425-434	10	Low	10
435-444	10	Medium	10
445-454	10	High	10
455-464	10	Very high	10
465-474	10	Unknown	10
475-484	10	Family size	
485-494	10	Small	10
495-504	10	Medium	10
505-514	10	Large	10
515-524	10	Health insurance	
525-534	10	Yes	10
535-544	10	No	10
545-554	10	Healthcare access	
555-564	10	Easy	10
565-574	10	Difficult	10
575-584	10	Unknown	10
585-594	10	Healthcare utilization	
595-604	10	Regular	10
605-614	10	Occasional	10
615-624	10	Never	10
625-634	10	Healthcare cost	
635-644	10	Low	10
645-654	10	Medium	10
655-664	10	High	10
665-674	10	Very high	10
675-684	10	Unknown	10
685-694	10	Healthcare quality	
695-704	10	Good	10
705-714	10	Fair	10
715-724	10	Poor	10
725-734	10	Very poor	10
735-744	10	Unknown	10
745-754	10	Healthcare satisfaction	
755-764	10	High	10
765-774	10	Medium	10
775-784	10	Low	10
785-794	10	Very low	10
795-804	10	Unknown	10
805-814	10	Healthcare accessibility	
815-824	10	Good	10
825-834	10	Fair	10
835-844	10	Poor	10
845-854	10	Very poor	10
855-864	10	Unknown	10
865-874	10	Healthcare affordability	
875-884	10	High	10
885-894	10	Medium	10
895-904	10	Low	10
905-914	10	Very low	10
915-924	10	Unknown	10
925-934	10	Healthcare effectiveness	
935-944	10	High	10
945-954	10	Medium	10
955-964	10	Low	10
965-974	10	Very low	10
975-984	10	Unknown	10
985-994	10	Healthcare equity	
995-1004	10	High	10
1005-1014	10	Medium	10
1015-1024	10	Low	10
1025-1034	10	Very low	10
1035-1044	10	Unknown	10
1045-1054	10	Healthcare safety</	

☒ Responsive to communication(s) filed on Nov 1, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 15 USPQ2d 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 23-44 _____ is/are pending in the applicat

~~Of these~~ Claim(s) 1-22 have been canceled. ~~is/are withdrawn from consideration~~

☒ Claim(s) 38-40 _____ is/are allowed.

☒ Claim(s) 23-26, 29-37, and 41-44 _____ is/are rejected.

☒ Claim(s) 27 and 28 _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

***Certified copies not received:**

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 11/1/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 29, 31, and 42-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These rejections are necessitated by amendment.

Claims 29 and 42 now cite a broader "filter" practice without the "high molecular weight filter" limitations as filed. This broader filter practice is NEW MATTER.

Claim 31, line 2, cites the word "adjacent" regarding the air pocket disposition compared to the transition region. Corresponding claim 9, as filed, contains the more limited limitation "surrounding" for this practice. The broader claim 31, "adjacent" practice, therefore is NEW MATTER.

Claims 43 and 44 now contain NEW MATTER in that claim 43, lines 1-3, cites the side channel as only communicating with the transition region whereas the corresponding disclosure in claim

21, as filed, requires that this side channel communicates for the specific purpose of adding reagents to the transition region. This lack of reagent addition practice for this side channel is a broadening of the claim practice and is therefore NEW MATTER.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 23, 30, and 35-37 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Wilding et al. (P/N 5,587,128).

This rejection is maintained and reiterated from the previous office action, mailed 6/6/00, and as necessitated by amendment regarding newly submitted claims. Applicants firstly argue that the device of Wilding et al. lacks a unitary body which encloses the reaction chamber and separation and transition region such as required in the definition of unitary in the specification and recited in claim 23. In response it is noted

that claim 23 cites a unitary body in which said chamber and regions are formed and enclosed. It is noted that the Wilding et al. device also contains formed and enclosed chambers and regions as claimed. Looking to the specification for a definition of unitary as argued by applicants reveals confusing and contradictory passages. It is acknowledged that in the specification on page 6, lines 18-20, that unitary is defined as being formed of a single piece of material. This would suggest that no assembly or sealing of covers etc. would be included in such a device. Confusingly, a review of the remainder of the instant specification reveals another embodiment for such a unitary device on page 20, lines 13-22, wherein a plastic film may be utilized to seal the opposite sides of a molded part to result in enclosure of said chamber and regions. This conflicts with the definition of unitary cited on page 6 of the instant specification. Since both are instantly disclosed, a reasonable interpretation is that unitary may include a sealed multi-part plastic device, for example. Wilding et al. at column 7, lines 28-32, as pointed to by applicants clearly describes such a device wherein a plastic cover may enclosed the device which itself may be formed of plastic. This fits the unitary device description in the instant specification on page 20 as noted above and supports this rejection. Applicants then argue that the instant transition region has a lower thermal conductivity to

isolate the reaction chamber from the separation region. In response all of the devices of Wilding et al. contain channels or transition regions connection chambers and regions for various functions including reaction and separation as previously set forth in the previous office action, mailed 6/6/00. The thermal isolation to permit different procedures in different sections of the Wilding et al. device has not been argued as to why this does not inherently support the concept of a lower thermal conductivity as required in the instant claims. Thus, applicants allegation regarding the lack of a statement is non-persuasive compared to the facts of these different functions are performed while being thermally isolated in the Wilding et al. disclosure. Thus, applicants have not argued the basis for the rejection on this point. Applicants then summarize the pertinent patent law and summarize the above arguments, but since the arguments have been answered as to being non-persuasive as explained above the rejection is maintained and applied to the corresponding newly submitted claims as necessitated by amendment.

Claims 23-26, 29, 30, 32-37, and 41-44 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Jerman (P/N 5,824,204).

This rejection is maintained and reiterated from the previous office action, mailed 6/6/00, and as necessitated by amendment regarding newly submitted claims. Applicants firstly

argue again the issue of what is meant by "unitary". In response the same response as given above is reiterated here in that the instant specification seems to contain various disclosures of what "unitary" means, one of which is via assembly as performed in the reference thus making this argument non-persuasive.

Applicants then argue that there is no flow restrictor in Jerman. In response the channels that connect the various chambers are small in dimension and clearly restrict flow. Applicants then argue that the transition region of Jerman does not have a lower thermal conductivity. As responded to in the above rejection the small channels clearly thermally isolate the various chambers and prevent thermal conduction between chambers or regions due to the mass of material which is present around these narrow channels. Applicants then repeat their arguments and restate them regarding unobviousness which is deemed moot as the rejection herein applied is one of anticipation. Applicants then discuss temperature gradient etc. regarding unobviousness but this is deemed to be moot again as the rejection is based on anticipation. Applicants then specifically argue that claim 16, previously pending, now claim 38 is not anticipated. Applicants first argument is again regarding the one-piece concept or "unitary" concept, but it is acknowledged that claim 38 now requires that the one-piece device both form and enclose the reaction chamber, transition and separation regions which is

persuasive to overcome the rejection of claim 38 based on Jerman. Applicants then argue claim 41-44 separately. Applicants first argument is directed to the flow restrictor and thermal isolation issues, both of which have been responded to above as being non-persuasive and are reiterated here. Applicants new argument is regarding a filter presence. In response Jerman utilizes electroosmotic movement between chambers as pointed to in the previous office action which discloses a practice which inherently filters the materials rather than mediates free flow. This method of movement inherently proceeds if the materials are retarded so as to be moved through a filtering medium via their charge content. Thus, filtering practice is disclosed in Jerman, albeit without explicitly citing the word "filter".

Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 38-40 are allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS

OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

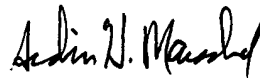
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 26, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER